

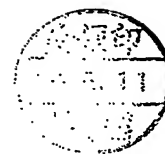
PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **10. 5. 2005**

Applicant's or agent's file reference
10003828WO01

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/JP2004/019763

International filing date (day/month/year)
24.12.2004

Priority date (day/month/year)
25.12.2003

International Patent Classification (IPC) or both national classification and IPC
Int.Cl.⁷ **C12N15/11, C12Q1/68**

Applicant
CANON KABUSHIKI KAISHA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Date of completion of this opinion		13.04.2005	
Name and mailing address of the ISA/JP Japan Patent Office 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan		Authorized officer	
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**WRITTEN OPINION OF THE
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Box No. 1 Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☒ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☒ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 1-4 (partial) and Nos. 5-22

because:

- ☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 1-4 (partial) and Nos. 5-22

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished
☐ does not comply with the standard

the computer readable form ☐ has not been furnished
☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions in that the computer readable form:

☐ has not been furnished
☐ does not comply with the technical requirements

- ☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

- ☐ paid additional fees
- ☐ paid additional fees under protest
- ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with
- ☒ not complied with for the following reasons:

See Supplemental Box.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-4 relevant to only a probe set
comprising the probe No.0 in Table 1-1

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3	YES
	Claims	1, 2, 4	NO
Inventive step (IS)	Claims	3	YES
	Claims	1, 2, 4	NO
Industrial applicability (IA)	Claims	1 - 4	YES
	Claims		NO

2. Citations and explanations

D1: Proc.Natl.Acad.Sci.USA (1996), Vol.93, p.10961-10965
D2: J.Exp.Med.(1995), Vol.182, No.6, p.1847-56
D3: J.Biomed.Biotechnol.(2003/Aug), Vol.2003, No.3, p.208-211
D4: Geno.Prot.Bioinfo.(2003/Nov), Vol.1, No.4, p.304-309
D5: Blood.(1999), Vol.94, No.4, p.1471-1477.

The subject matter of claims 1, 2 and 4 does not meet the requirement of novelty.

The closest prior document D1 cited in the international search report discloses a probe set comprising probes that can be used for identification of HLA-A, HLA-B, and HLA-C alleles which is regarded to fall within the definition in the present Claim 1,2 and 4.

The subject matter of claims 3 relevant to only a probe set comprising the probe No.0 in Table 1-1 meets the requirements with respect to novelty and inventive step.

D1 discloses a probe set comprising probes that can be used for identification of HLA-A, HLA-B, and HLA-C alleles.

However, D1 does not disclose specific nucleotide sequence contained in the probe No.0 in Table 1-1. In addition to that, such a sequence is neither disclosed in any of the documents D1-D5 cited in the ISR nor obvious to a person skilled in the art.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. IV

There are 1899 groups of inventions which is contained in claim 1-22: <Group 1-1899>each probe sets comprising at least one probe comprised a partial sequence in a sequence listed in Tables 1-1 to 28-2 that can be used for identification of an allele of specific HLA antigen gene(e.g. HLA-A)

The separate groups of inventions are not so linked as to form a single general inventive concept for the following reasons:

The same technical feature among the probe sets comprising at least one probe comprised a partial sequence in a sequence listed in Tables 1-1 to 28-2 that can be used for identification of an allele of specific HLA antigen gene(e.g. HLA-A) is "a probe set comprising probes that can be used for identification of a HLA allele".

However, "a probe set comprising probes that can be used for identification of HLA-A, HLA-B, and HLA-C alleles" is disclosed in the Table 1 of D1, and "a probe set comprising probes that can be used for identification of HLA-DP alleles" is disclosed in the claim 2 of D2, and "a probe set comprising probes that can be used for identification of HLA-A, and HLA-B alleles" is disclosed in the claim 12-17 of D3. So this feature is not new, and a contribution of this feature is not over the prior art.

And there are no other technical features which are the same or corresponding among the groups of inventions which is contained in the claims, and a contribution of those features are over the prior art.

Therefore there are no technical relationship which is considered as "special technical feature" (PCT rule 13.2) among the groups of claims.

D1:Proc.Natl.Acad.Sci.USA (1996), Vol.93, p.10961-10965

D2:JP 6-78800 A (1994.03.22)

D3:EP 540997 A1 (1992.10.28)